

STATE OF MISSOURI



PERMIT BOOK

DEPARTMENT OF NATURAL RESOURCES

MISSOURI AIR CONSERVATION COMMISSION

PERMIT TO CONSTRUCT

Under the authority of RSMo 643 and the Federal Clean Air Act the applicant is authorized to construct the air contaminant source(s) described below, in accordance with the laws, rules and conditions as set forth herein.

Permit Number: 022016-014

Project Number: 2015-06-048  
Installation Number: 031-0068

Parent Company: Midwest Sterilization Corporation

Parent Company Address: 1204 Lenco Avenue, Jackson, MO 63755

Installation Name: Midwest Sterilization Corporation

Installation Address: 1204 Lenco Avenue, Jackson, MO 63755

Location Information: Cape Girardeau County, S14, T35N, R7E

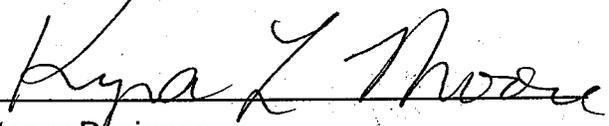
Application for Authority to Construct was made for:

The installation of two sterilization chambers. This review was conducted in accordance with Section (5), Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*.

Standard Conditions (on reverse) are applicable to this permit.

Standard Conditions (on reverse) and Special Conditions are applicable to this permit.

  
Prepared by  
Chia-Wei Young  
New Source Review Unit

  
Director or Designee  
Department of Natural Resources

FEB 25 2016

Effective Date

## STANDARD CONDITIONS:

Permission to construct may be revoked if you fail to begin construction or modification within two years from the effective date of this permit. Permittee should notify the Air Pollution Control Program if construction or modification is not started within two years after the effective date of this permit, or if construction or modification is suspended for one year or more.

You will be in violation of 10 CSR 10-6.060 if you fail to adhere to the specifications and conditions listed in your application, this permit and the project review. In the event that there is a discrepancy between the permit application and this permit, the conditions of this permit shall take precedence. Specifically, all air contaminant control devices shall be operated and maintained as specified in the application, associated plans and specifications.

You must notify the Department's Air Pollution Control Program of the anticipated date of start up of these air contaminant sources. The information must be made available within 30 days of actual startup. Also, you must notify the Department of Natural Resources' regional office responsible for the area within which you are located within 15 days after the actual start up of these air contaminant sources.

A copy of this permit and permit review shall be kept at the installation address and shall be made available to Department of Natural Resources' personnel upon request.

You may appeal this permit or any of the listed special conditions to the Administrative Hearing Commission (AHC), P.O. Box 1557, Jefferson City, MO 65102, as provided in RSMo 643.075.6 and 621.250.3. If you choose to appeal, you must file a petition with the AHC within 30 days after the date this decision was mailed or the date it was delivered, whichever date was earlier. If any such petition is sent by registered mail or certified mail, it will be deemed filed on the date it is mailed. If it is sent by any method other than registered mail or certified mail, it will be deemed filed on the date it is received by the AHC.

If you choose not to appeal, this certificate, the project review and your application and associated correspondence constitutes your permit to construct. The permit allows you to construct and operate your air contaminant sources(s), but in no way relieves you of your obligation to comply with all applicable provisions of the Missouri Air Conservation Law, regulations of the Missouri Department of Natural Resources and other applicable federal, state and local laws and ordinances.

The Air Pollution Control Program invites your questions regarding this air pollution permit. Please contact the Construction Permit Unit at (573) 751-4817. If you prefer to write, please address your correspondence to the Missouri Department of Natural Resources, Air Pollution Control Program, P.O. Box 176, Jefferson City, MO 65102-0176, attention: Construction Permit Unit.

**SPECIAL CONDITIONS:**

The permittee is authorized to construct and operate subject to the following special conditions:

*The special conditions listed in this permit were included based on the authority granted the Missouri Air Pollution Control Program by the Missouri Air Conservation Law (specifically 643.075) and by the Missouri Rules listed in Title 10, Division 10 of the Code of State Regulations (specifically 10 CSR 10-6.060). For specific details regarding conditions, see 10 CSR 10-6.060 paragraph (12)(A)10. "Conditions required by permitting authority."*

Midwest Sterilization Corporation  
Cape Girardeau County, S14, T35N, R7E

1. Ethylene Oxide Usage Limitations
  - A. Midwest Sterilization Corporation shall not use more than the following amount of ethylene oxide in any consecutive 12-month period.

**Table 1: Allowable Ethylene Oxide Usage**

<b>Chamber Numbers</b>	<b>Allowable Ethylene Oxide (lb/yr)</b>
1 through 6	<sup>1</sup> 236,520
7, 8	<sup>1</sup> 124,392
9, 11	<sup>1</sup> 326,857
12	12,866
13	5,146

Note 1: The allowable ethylene oxide usage (lb/yr) is the total of all chambers combined, not individual chambers.

- B. Attachment A or equivalent forms, such as electronic forms, shall be used to demonstrate compliance with Special Conditions 1.A.
2. Control Device Requirement – Wet Scrubber
  - A. Midwest Sterilization Corporation shall control emissions from the vacuum pump vents of the new sterilization chambers (EU-12 and EU-13) using a wet scrubber (EP-1) as specified in the permit application.
  - B. The wet scrubber shall be operated and maintained in accordance with the manufacturer's specifications, a copy of which shall be kept on-site.
  - C. The operating pressure drop and the liquid flow rate of the scrubber shall be maintained within the manufacturer's recommended operating conditions (40-120 gpm for liquid flow rate, 10-17 wg for pressure drop).
  - D. Midwest Sterilization Corporation shall install gauges to measure the scrubber pressure drop and the liquid flow rate. The operating pressure drop and the liquid flow rate shall be recorded once every day while the scrubber is in operation to show compliance with Special Condition 2.C.

**SPECIAL CONDITIONS:**

The permittee is authorized to construct and operate subject to the following special conditions:

- E. The concentration of glycol in the wet scrubber liquor shall not exceed 49.5% by weight, which was established during the September 15, 2004 stack test. Midwest Sterilization Corporation shall sample the wet scrubber liquor once each week to verify that the concentration of glycol is not greater than 49.5% by weight. Sampling shall be performed using methods approved by the Missouri Air Pollution Control Program.
  - F. If the glycol concentration for any sample tested in compliance with Special Condition 2.E., is greater than 49.5% by weight, Midwest Sterilization shall implement corrective actions to return the concentration to less than or equal to 49.5%. If corrective actions fail to return the concentration of less than or equal to 49.5%, Midwest Sterilization Corporation shall submit an application to the Air Pollution Control Program to take into account the new information.
  - G. Midwest Sterilization Corporation shall maintain an operating and maintenance log for the wet scrubber which shall include the following:
    - 1) Incidents of malfunction, with impact on emissions, duration of event, probable cause, and corrective actions; and
    - 2) Maintenance activities, with inspection schedule, repair actions, and replacements, etc.
3. Record Keeping and Reporting Requirements
- A. Midwest Sterilization Corporation shall maintain all records required by this permit for not less than five years and shall make them available immediately to any Missouri Department of Natural Resources' personnel upon request. These records shall include SDS for all materials used.
  - B. Midwest Sterilization Corporation shall report to the Air Pollution Control Program's Compliance/Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, no later than 10 days after the end of the month during which any record required by this permit show an exceedance of a limitation imposed by this permit.

REVIEW OF APPLICATION FOR AUTHORITY TO CONSTRUCT AND OPERATE  
SECTION (5) REVIEW

Project Number: 2015-06-048  
Installation ID Number: 031-0068  
Permit Number:

Installation Address:  
Midwest Sterilization Corporation  
1204 Lenco Avenue  
Jackson, MO 63755

Parent Company:  
Midwest Sterilization Corporation  
1204 Lenco Avenue  
Jackson, MO 63755

Cape Girardeau County, S14, T35N, R7E

REVIEW SUMMARY

- Midwest Sterilization Corporation has applied for authority to install one 267 cubic feet sterilization chamber and one 72 cubic feet sterilization chamber.
- The application was deemed complete on June 15, 2015.
- HAP emissions are expected from the proposed equipment. The HAP of concern from this process is ethylene oxide.
- None of the New Source Performance Standards (NSPS) apply to the installation.
- None of the NESHAPs apply to this installation.
- 40 CFR 63, Subpart O, *Ethylene Oxide Emissions Standards for Sterilization Facilities*, of the MACT applies to the installation.
- A wet scrubber is being used to control the emissions from vacuum pump vent of the sterilization chambers.
- This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*. Potential emissions of all pollutants are below de minimis levels.
- This installation is located in Cape Girardeau County, an attainment area for all criteria pollutants.
- This installation is not on the List of Named Installations found in 10 CSR 10-6.020(3)(B), Table 2. The installation's major source level is 250 tons per year and fugitive emissions are not counted toward major source applicability.

- Ambient air quality modeling was not performed. The potential emissions of ethylene oxide, a HAP, is greater than the SMAL of 0.1 tpy. However, the EPA has completed the Risk and Technology Review for sterilization facilities, and ambient air quality modeling is not required.
- Emissions testing is not required for the equipment.
- An operating permit is not required for this installation even though 40 CFR 63, Subpart O, *Ethylene Oxide Emissions Standards for Sterilization Facilities*, of the MACT applies to the installation. Per 40 CFR §63.360(f), “If you are an owner or operator of an area source subject to this subpart, you are exempt from the obligation to obtain a permit under 40 CFR Part 70 or 71, provided you are not required to obtain a permit under 40 CFR 70.3(a) or 71.3(a) for a reason other than your status as an area source under this subpart.” Because EPA has made a decision with respect to the need to obtain a Part 70 Operating Permit, the installation in this case does not need to obtain a Basic Operating Permit either.
- Approval of this permit is recommended with special conditions.

## INSTALLATION DESCRIPTION

Midwest Sterilization Corporation is an existing installation in Jackson, Missouri that sterilizes disposable medical devices, dairy cartons, and spices. The largest portion of the business is sterilization of plastic medical supplies. The sterilization process uses ethylene oxide, which is converted to liquid ethylene glycol after wet scrubbing.

The facility currently operates eleven (11) sterilization chambers and 21 aeration rooms. Chambers one (1) through six (6) are each approximately 1,000 cubic feet (cf) capacity. Chambers seven (7) and eight (8) are approximately 2,000 cf capacity. Chambers nine (9), ten (10), and eleven (11) are each 4,423 cf capacity.

The sterilization process begins with the loading of palletized, non-sterile products into a designated preconditioning room where they are held under elevated temperature and humidity levels for a prescribed amount of time in preparation for sterilization. After the preconditioning step, the load is transferred using forklifts to a sterilization chamber. While in the chamber, vacuum pumps are used to execute a number of evacuations to reduce the concentration of oxygen inside. Nitrogen, steam, and subsequently, a known amount of ethylene oxide are then introduced into the chamber under a vacuum and circulated in and around the product for a specified period of time. The chamber temperature is maintained at about 125 °F by hot water jackets that wrap the chamber.

After sterilization, vacuum pumps are used to remove the ethylene oxide from the chamber and route it to the wet scrubber emission control system. A number of flush cycles are required during the evacuation process to reduce the ethylene oxide to a level that allows for safe chamber unloading. When the sterilization chamber door is opened for unloading, a vent on the opposite end of the chamber (the back vent) automatically activates an exhaust fan that pulls fresh warehouse air through the

chamber during the entire unloading process. The back vent, as allowed by 40 CFR 63, Subpart O, is uncontrolled and exhausts to the atmosphere.

The sterilized product is moved from the chamber to a heated aeration room. During a typical 24-72 hour period of time, the aeration process removes residual ethylene oxide from the product. The aeration room emissions are directed through a Safe Cell II emission control system that consists of a series of DR 490 units filled with dry reactant that reduces the ethylene oxide emissions to levels that comply with the applicable 40 CFR Subpart O requirements. When aeration is complete, the sterilized product is stored in the sterile area of the warehouse before shipping.

Table 2 below lists the average amount of ethylene oxide charged during each cycle for the existing chambers.

**Table 2: Amount of Ethylene Oxide Charged**

Chamber Size (cf)	Ethylene Charged (lb/cycle)
1,000	54
2,000	142
4,423	199

The installation is a minor source for construction permits and a basic source for operating permits. The following New Source Review permits have been issued to Midwest Sterilization Corporation from the Air Pollution Control Program.

**Table 3: Permit History**

Permit Number	Description
0780-006	Permitting sterilization chambers.
0187-003	Changing location.
0389-011	Installation of new sterilization chambers.
0490-002	Installation of new sterilization chambers.
1094-005	Addition of new sterilization chambers.
062000-011	Addition of new sterilization chambers, aeration rooms, and ethylene oxide abatement system.
062003-023	Installation of one sterilization chamber and three aeration rooms.
062003-023A	Removing language.
052004-009	New process configuration for MACT compliance.
052004-009A	Removing and replacing special conditions. Added emissions limit.
052004-009B	Limit ethylene oxide emissions and revise back vent emission limit.
122013-007	Addition of a sterilization chamber.

## PROJECT DESCRIPTION

The installation proposes to add one 267 cf and one 72 cf sterilization chamber, which will be designated chambers 12 and 13, respectively. Previously, the facility had designated two other 4,423 cf chambers as numbers 11 and 12. However, these chambers were decommissioned and relocated to the company's Laredo, Texas sterilization facility. Table 4 below gives information on the two new sterilization chambers.

**Table 4: Process Information for Chambers 12 and 13.**

Description	Units	Chamber 12	Chamber 13
Average Cycle Duration	Hours	9.6	8.0
Average Ethylene Oxide Usage	Lb/cycle	14.1	4.7
Maximum Cycle Per Day	Cycle/Day	2.5	3.0
Ethylene Oxide Usage	Lb/year	12,690	5,076

Ethylene oxide in the new chambers will be pumped to the same wet scrubber (E-1) as the other existing chambers. Sterilized products will be sent to the existing aeration rooms that are controlled by the safe cell ethylene oxide control system. No additional aeration rooms will be installed. Although potential emissions from the aeration rooms will increase due to the additional sterilization chambers, no special condition is written in this permit for the use of the Safe Cell II emissions control system because Permit No. 122013-007 already requires the use of the Safe Cell II system on the aeration rooms. Three existing natural-gas fired boilers will be used to supply the hot water that maintains the temperature in the chambers.

#### EMISSIONS/CONTROLS EVALUATION

Ethylene oxide, which is both a VOC and a HAP, will be emitted from the chambers. Emissions were calculated from mass balances and MACT limits. For the back vents, Permit 052004-009B required that testing be performed on some of the existing sterilization chambers to ensure that the concentration of ethylene oxide emitted are less than 0.008 pounds of ethylene oxide emitted per pound of ethylene oxide charged. Performance testing conducted in 2005 shows compliance with this limit. Since the new chambers undergoes the same process, the 0.008 lb ethylene oxide emitted/lb ethylene charged was also used to calculate emissions from the back vents.

In MACT Subpart O, the aeration room vents are required to have either 99% control or 1 ppm ethylene oxide concentration, whichever is less stringent. According to the company, the 1 ppm concentration limit is the less stringent. Therefore, emissions from the aeration room vents were calculated using the 1 ppm concentration and the Safety Cell exhaust maximum flow rate of 40,000 cfm.

For the sterilization chamber vacuum vents, ethylene oxide emissions were calculated using mass balances and a scrubber efficiency of 99.73%, which was verified during a compliance test performed in 2004. Since the natural-gas fired boilers are existing equipment, their emissions were not considered during the review of this project. PM<sub>2.5</sub>, PM<sub>10</sub>, and PM emissions from the haul road were calculated using emission factors calculated from equations found in Environmental Protection Agency (EPA) document AP-42, *Compilation of Air Pollutant Emission Factors, Volume 1: Stationary Point and Area Source*, 5<sup>th</sup> Edition, Chapter 13.2.2, *Unpaved Roads*, (11/06). No control is being used on the haul road.

The following table provides an emissions summary for this project. Existing potential emissions of PM<sub>2.5</sub>, PM<sub>10</sub>, and PM are taken from Permit No. 122013-007. Existing potential emissions of all other pollutants were recalculated using updated numbers. The ethylene oxide usages for existing chambers supplied by the installation were different than those used in previous permits. Therefore, a special condition (No. 1.A.) is written in this permit to limit the ethylene oxide usage to ensure the accuracy of the existing emissions calculations. Existing actual emissions were taken from the installation's 2014 EIQ. Potential emissions of the application represent the potential of the new equipment assuming continuous operation (8760 hours per year).

**Table 5: Emissions Summary (tons per year)**

Pollutant	Regulatory <i>De Minimis</i> Levels	Existing Potential Emissions	Existing Actual Emissions (2014 EIQ)	Potential Emissions of the Application	New Installation Conditioned Potential
PM	25.0	2.40	N/D	2.24	N/A
PM <sub>10</sub>	15.0	1.14	0.32	0.64	N/A
PM <sub>2.5</sub>	10.0	0.56	N/D	0.06	N/A
SOx	40.0	0.04	0.01	N/A	N/A
NOx	40.0	6.47	1.72	N/A	N/A
VOC	40.0	5.21	2.27	2.45	N/A
CO	100.0	5.43	1.44	N/A	N/A
GHG (CO <sub>2</sub> e)	75,000	7,808	N/D	N/A	N/A
GHG (mass)	0.0	7,762	N/D	N/A	N/A
Ethylene Oxide	0.1	4.85	N/D	2.45	N/A
HAPs	10.0/25.0	4.97	N/D	2.45	N/A

N/A = Not Applicable; N/D = Not Determined

### PERMIT RULE APPLICABILITY

This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*. Potential emissions of all pollutants are below de minimis levels.

### APPLICABLE REQUIREMENTS

Midwest Sterilization Corporation shall comply with the following applicable requirements. The Missouri Air Conservation Laws and Regulations should be consulted for specific record keeping, monitoring, and reporting requirements. Compliance with these emission standards, based on information submitted in the application, has been verified at the time this application was approved. For a complete list of applicable requirements for your installation, please consult your operating permit.

## GENERAL REQUIREMENTS

- *Submission of Emission Data, Emission Fees and Process Information*, 10 CSR 10-6.110
- *Restriction of Emission of Odors*, 10 CSR 10-6.165

## SPECIFIC REQUIREMENTS

- *MACT Regulations*, 10 CSR 10-6.075
  - *Ethylene Oxide Emissions Standards for Sterilization Facilities*, 40 CFR Part 63, Subpart O

## STAFF RECOMMENDATION

On the basis of this review conducted in accordance with Section (5), Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*, it is recommended that this permit be granted with special conditions.

## PERMIT DOCUMENTS

The following documents are incorporated by reference into this permit:

- The Application for Authority to Construct form, dated June 3, 2015, received June 15, 2015, designating Midwest Sterilization Corporation as the owner and operator of the installation.



## APPENDIX A

### Abbreviations and Acronyms

<b>%</b> .....	percent	<b>m/s</b> .....	meters per second
<b>°F</b> .....	degrees Fahrenheit	<b>Mgal</b> .....	1,000 gallons
<b>acfm</b> .....	actual cubic feet per minute	<b>MW</b> .....	megawatt
<b>BACT</b> .....	Best Available Control Technology	<b>MHDR</b> .....	maximum hourly design rate
<b>BMPs</b> .....	Best Management Practices	<b>MMBtu</b> ....	Million British thermal units
<b>Btu</b> .....	British thermal unit	<b>MMCF</b> .....	million cubic feet
<b>CAM</b> .....	Compliance Assurance Monitoring	<b>MSDS</b> .....	Material Safety Data Sheet
<b>CAS</b> .....	Chemical Abstracts Service	<b>NAAQS</b> ...	National Ambient Air Quality Standards
<b>CEMS</b> .....	Continuous Emission Monitor System	<b>NESHAPs</b>	National Emissions Standards for Hazardous Air Pollutants
<b>CFR</b> .....	Code of Federal Regulations	<b>NO<sub>x</sub></b> .....	nitrogen oxides
<b>CO</b> .....	carbon monoxide	<b>NSPS</b> .....	New Source Performance Standards
<b>CO<sub>2</sub></b> .....	carbon dioxide	<b>NSR</b> .....	New Source Review
<b>CO<sub>2e</sub></b> .....	carbon dioxide equivalent	<b>PM</b> .....	particulate matter
<b>COMS</b> .....	Continuous Opacity Monitoring System	<b>PM<sub>2.5</sub></b> .....	particulate matter less than 2.5 microns in aerodynamic diameter
<b>CSR</b> .....	Code of State Regulations	<b>PM<sub>10</sub></b> .....	particulate matter less than 10 microns in aerodynamic diameter
<b>dscf</b> .....	dry standard cubic feet	<b>ppm</b> .....	parts per million
<b>EQ</b> .....	Emission Inventory Questionnaire	<b>PSD</b> .....	Prevention of Significant Deterioration
<b>EP</b> .....	Emission Point	<b>PTE</b> .....	potential to emit
<b>EPA</b> .....	Environmental Protection Agency	<b>RACT</b> .....	Reasonable Available Control Technology
<b>EU</b> .....	Emission Unit	<b>RAL</b> .....	Risk Assessment Level
<b>fps</b> .....	feet per second	<b>SCC</b> .....	Source Classification Code
<b>ft</b> .....	feet	<b>scfm</b> .....	standard cubic feet per minute
<b>GACT</b> .....	Generally Available Control Technology	<b>SDS</b> .....	Safety Data Sheet
<b>GHG</b> .....	Greenhouse Gas	<b>SIC</b> .....	Standard Industrial Classification
<b>gpm</b> .....	gallons per minute	<b>SIP</b> .....	State Implementation Plan
<b>gr</b> .....	grains	<b>SMAL</b> .....	Screening Model Action Levels
<b>GWP</b> .....	Global Warming Potential	<b>SO<sub>x</sub></b> .....	sulfur oxides
<b>HAP</b> .....	Hazardous Air Pollutant	<b>SO<sub>2</sub></b> .....	sulfur dioxide
<b>hr</b> .....	hour	<b>tph</b> .....	tons per hour
<b>hp</b> .....	horsepower	<b>tpy</b> .....	tons per year
<b>lb</b> .....	pound	<b>VMT</b> .....	vehicle miles traveled
<b>lbs/hr</b> .....	pounds per hour	<b>VOC</b> .....	Volatile Organic Compound
<b>MACT</b> .....	Maximum Achievable Control Technology		
<b>µg/m<sup>3</sup></b> .....	micrograms per cubic meter		

Mr. Douglas Tropf  
Regulatory Affairs Manager  
Midwest Sterilization Corporation  
P.O. Box 411  
Jackson, MO 63755

RE: New Source Review Permit - Project Number: 2015-06-048

Dear Mr. Tropf:

Enclosed with this letter is your permit to construct. Please study it carefully and refer to Appendix A for a list of common abbreviations and acronyms used in the permit. Also, note the special conditions, if any, on the accompanying pages. The document entitled, "Review of Application for Authority to Construct," is part of the permit and should be kept with this permit in your files. Operation in accordance with these conditions and your new source review permit application is necessary for continued compliance. The reverse side of your permit certificate has important information concerning standard permit conditions and your rights and obligations under the laws and regulations of the State of Missouri.

If you were adversely affected by this permit decision, you may be entitled to pursue an appeal before the administrative hearing commission pursuant to Sections 621.250 and 643.075.6 RSMo. To appeal, you must file a petition with the administrative hearing commission within thirty days after the date this decision was mailed or the date it was delivered, whichever date was earlier. If any such petition is sent by registered mail or certified mail, it will be deemed filed on the date it is mailed; if it is sent by any method other than registered mail or certified mail, it will be deemed filed on the date it is received by the administrative hearing commission, whose contact information is: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65102, phone: 573-751-2422, fax: 573-751-5018, website: [www.ao.mo.gov/ahc](http://www.ao.mo.gov/ahc). If you have any questions regarding this permit, please do not hesitate to contact Chia-Wei Young, at the Department of Natural Resources' Air Pollution Control Program, P.O. Box 176, Jefferson City, MO 65102 or at (573) 751-4817. Thank you for your attention to this matter.

Sincerely,

**AIR POLLUTION CONTROL PROGRAM**

Susan Heckenkamp  
New Source Review Unit Chief

SH:cyl

Enclosures

c: Southeast Regional Office  
PAMS File: 2015-06-048  
Permit Number: